



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

939542

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: FEI 1000134995

April 8, 2003

Hector Lapuyade, President
Marcel and Henri Select Meats, Inc.
415 Browning Way
South San Francisco, California 94080

WARNING LETTER

Dear Mr. Lapuyade:

On December 10, 11, 12, 17, 24, and 27, 2002, we inspected your seafood processing facility located at 415 Browning Way, South San Francisco, California. We found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated ready-to-eat vacuum packed Seafood Sausages and Smoked Salmon Mousse are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plans for Seafood Sausage and Smoked Salmon Mousse do not list the food safety hazard of *Clostridium botulinum* growth and toxin formation in refrigerated, ready-to-eat, vacuum packed products. Additionally, your Seafood Sausage HACCP plan does not list the food safety hazard of undeclared sulfites associated with the shrimp ingredient.
2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan, that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plans for Seafood Sausage and Smoked Salmon Mousse do not list the critical control point of "Finished Product Cooler Storage" for controlling the food safety hazard of pathogen growth and toxin formation, as a result of time/temperature abuse.
3. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plans for Seafood Sausage and Smoked Salmon Mousse:
 - List a critical limit at the Cooking critical control point (CCP) that is not adequate to control pathogen survival through cooking. Your firm's HACCP plans list a critical limit at the Cooking CCP of cooking the product until it reaches an

internal temperature of [REDACTED]°F. The FDA recommends that the critical limits at your Cooking critical control point include a time and temperature combination of your cooking process. For example, you could ensure that your product reaches an internal temperature of [REDACTED]°F for at least 20 minutes. A scientific study of your cook cycles and equipment can help you best determine what limits should be implemented to insure the overall safety of your products.

- List temperature reduction critical limits at the Cooling Cooked Product critical control point that are not adequate to control pathogen growth and toxin formation as a result of time/temperature. Your firm cites a critical limit at the Cooling CCP of cooling the Seafood Sausage and Smoked Salmon Mousse from [REDACTED]°F to [REDACTED]°F within [REDACTED] hours and from [REDACTED]°F to [REDACTED]°F in [REDACTED] hours. The FDA recommends that the products be cooled from 140°F to 70°F within 2 hours and to 40°F or below within another 4 hours. Information on cooling after cooking may be found in the Fish & Fishery Products Hazards & Controls Guidance, Third Edition, Chapter 12, page 154.

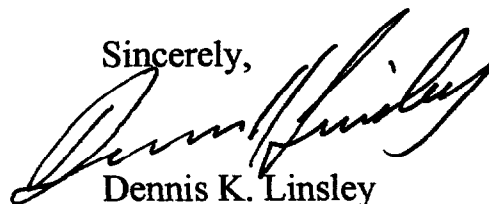
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, revised HACCP plans, or other useful information that would assist us in evaluating your corrections. If you cannot complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all of the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulation (21 Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley
District Director
San Francisco District

cc: Henri J. Lapuyade